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11/25/02

Office of Public Health & Science & FDA, HHS  
Dockets Management Branch (HFA-305)  
Docket Number: 02N-0466  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**Solicitation of Public Review and Comment on Research Protocol: A  
Multicenter, Randomized Dose Response Study of the Safety, Clinical and  
Immune Response of Dryvax Administered to Children 2 to 5 Years of Age.**

**To whom it may concern:**

**I strongly believe that administering the smallpox vaccination to 40 healthy children between the ages of 2 to 5 is unsafe and unethical. There are serious, if not fatal side effects and there are no medical benefits unless they are exposed to a bioterrorist attack.**

**Research from the 1960's shows that 15 out of every 1 million American's vaccinated will get life-threatening illnesses and 1 or 2 will die. These numbers may be lower or higher with today's vaccine but, whatever the case it is still too high of a risk.**

**The following are some serious risks: If the vaccinated child somehow removes the protective bandage from the injection site they can spread the virus by touching their own mucus membranes or someone else's. If spread into the eye, blindness can occur. Family and friends can be at risk because they are not vaccinated and there are no statistics on how they will be effected if adequately exposed to child. Person's with weak immune systems, such as AIDS patients, could die from being exposed to virus. How will they be notified and protected?**

**The other negative issue is that the children will be removed from daycare and school for 1 month prior to vaccination. This raises many questions; Who will watch the children if their parents work? How will learning be continued? How will they make up what they miss? How will**

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their social needs be met when taken away from their peers? This is a very developmental time for children and if interfered with, long-term problems could be put in place.

The sample population is too young to know and understand what is happening. It is not like other vaccines they have received. They are at the age where if something is irritating them, they will change it themselves or scream and cry until someone does. Do you know any toddler that wants a painful, itchy scab with a bubble band-aid covering it? I don't.

Another issue that arises is that 40 children is not enough to get valid results that represents their age group. There are 280 million American's and a large amount of them are between the sample populations ages. 40, is just simply not enough.

The only Pro's to this study would be; The fact that a bioterrorist attack is a real present threat, and unless some type of study is done, we don't know how to protect our children. Also, parents want advice on this issue and recent studies are the only 100% accurate way to give it to them.

Even though there is some good to this proposed study, it is not enough to out-weigh the bad. Giving any amount of children this vaccine for no medical benefit is unsafe and unethical, period. Besides, who would volunteer their child to do so, would you?

*Nicole Maldera*